VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted for

AESCULAP®, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034
Telephone: (610) 797-9300
Contact: Joyce Thomas, Director of Regulatory Affairs & Quality Assurance
Date Prepared: May 2, 2001

B. Device Name

Trade or Proprietary Name:	*Monosyn®* Synthetic Absorbable Surgical Suture
Common or Usual Name:	Synthetic AbsorbableSurgical Suture
Classification Name:	Absorbable Poly(Glycolide/L-lactide) Surgical Suture

C. Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- BIOSYN® Synthetic Absorbable Surgical Suture (U. S. Surgical Corp.)
- MONOCRYL® Synthetic Absorbable Surgical Suture (Ethicon, Inc.)

D. Device Description

The subject device is an absorbable, flexible monofilament suture thread which is supplied sterile. It is composed of a synthetic polyglycolic acid-based copolymer, and is indicated for soft tissue approximation and/or ligation, but not for cardiovascular or neurological surgery. It will be offered undyed, and dyed with the FDA approved colorant D&C Violet No. 2 in accordance with Title 21 CFR, §74.3602. It is available uncoated, and will be available with or without standard needles attached.

E. Intended Use

Monosyn® Synthetic Absorbable Surgical Suture is indicated for use in soft tissue approximation and/or ligation, but not for cardiovascular or neurological surgery.

F. Comparison to Predicate Devices

Monosyn® Synthetic Absorbable Surgical Suture is a terpolymer composed primarily of polyglycolic acid and other material constituents identical to those comprising the predicate MONOCRYL® and/or BIOSYN® sutures. Further, the subject device is offered either undyed, or dyed with the same colorant as the predicate devices, that being D&C Violet No. 2, at a concentration that conforms to the requirements of Title 21 CFR, §74.3602.

The subject device has the same design as do the MONOCRYL® and BIOSYN® predicate devices, being a sterile, flexible monofilament thread.

The subject suture is offered in a variety of lengths and a range of diameters conforming, and is offered with or without one of a selection of standard needles attached. Further, as is the case with the predicate devices, the subject device conforms in all respects to the requirements of the Official Monograph for Absorbable Surgical Suture in U.S.P. XXIV, including <861> *Sutures -- Diameter*, <871> *Sutures -- Needle Attachment*, and <881> *Tensile Strength*, excepting minor variations in diameter.

Physical properties of the subject device are substantially equivalent to those of the MONOCRYL® and BIOSYN® predicate devices, including suture diameter, knot pull tensile strength, needle attachment strength, linear tensile strength, tissue drag, flexibility, elongation, and knot elongation, among others.

The subject device is manufactured in a manner typical of the industry and equivalent to that used to produce predicate devices, wherein prepolymers of the copolymeric constituents are synthesized, and the chains are then "capped" with polyglycolide segments. The polymer is then melt extruded (colorant is added if desired) and spun to form monofilaments of specified diameter, and then drawn to enhance tensile properties. The fibers are then cut to length and attached to needles.

Given that the subject device is made from the same materials, and in the same manner, as the predicate devices, the subject device has the equivalent chemical characteristics, biocompatibility, and *in vivo* performance properties as do the predicate devices. The subject device is packaged and sterilized in the same or equivalent manner, and has the same or equivalent labeling claims as do the predicate devices, including indications, contraindications, warnings, cautions and precautions.

G. Summary of Non-Clinical Tests

Non-clinical testing conducted on the subject device to demonstrate its substantial equivalence to predicate devices included physical testing for all parameters identified above, sterilization validation and evaluation of sterilant residues, and shelf-life testing. Testing conducted by the manufacturer included testing of physical properties to prove conformance to the requirements of U.S.P., *in vitro* and *in vivo* biosafety studies, and implant studies in animals to demonstrate rates of tensile strength and mass loss.

H. Summary of Clinical Tests

(Not applicable)

I. Conclusions of Non-Clinical and Clinical Tests

The results of all testing demonstrated the substantial equivalence, if not superiority, of the subject device to one or more predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2001

Aesculap, Inc.
c/o Mr. Steve Reitzler
Steve Reitzler, RAC
13221 Maricotte Place
San Diego, California 92130

Re: K011375
Trade/Device Name: AESCULAP®, Inc. Monosyn® Synthetic Absorbable Suture
Regulation Number: 878.4493
Regulatory Class: II
Product Code: GAM
Dated: May 2, 2001
Received: May 4, 2001

Dear Mr. Reitzler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K011375

Device Name: AESCULAP®, Inc, *Monosyn®* Synthetic Absorbable Suture

Indications for Use:

Monosyn® *Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery.*

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011375

Prescription Use √ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)